

REMARKS

Claims 1, 3, 4, 6, 7 and 9-52 are pending in this patent application with claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43, and 46 being the independent claims.

Based on the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections Under 35 U.S.C. 112

Claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that those claims contain subject matter that was not described in the specification at the time of filing. Specifically, the Examiner asserts that phrase “predetermined configuration” added in the previously submitted claim amendment was not supported by the original disclosure. As support, the Examiner states that “the specification describes only embodiments wherein the articles are ‘disposed’ in a container” and that “[t]here is no mention of placing them in a ‘predetermined configuration,’ which phrase implies a predetermined order.”

The invention recited in the rejected claims includes a fixture that is mounted external to a container holding a plurality of articles. As described throughout the specification as filed, the characteristics of the fixtures correspond to the irregularities in the geometrical and/or density characteristics of the articles that are irradiated. The fixture is aligned with the articles so that the dosage received by the article is maintained within radiation limits.

Support for the addition of “predetermined configuration” in the previous amendment was present in the application as filed. First, FIGS. 6 and 7 clearly show the fixtures (44, 46 and 52) aligned with articles that are held in a predetermined configuration, e.g., in parallel, in

containers. Second, that feature is inherent in the description, because the articles would have to be held in a predetermined configuration within the container in order to align properly with the fixtures coupled to the outside of the container. The Applicants request that the Examiner reconsider this rejection accordingly.

Rejections Under 35 U.S.C. 103(a)

Claims 1, 3, 4, 6, 7, 9-15, 17-35, and 37-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over reference JP 200312708 to Doi (“Doi”) in view of U.S. Patent No. 6,030,554 to Ichihara (“Ichihara”). The Examiner states “Doi is silent with respect to a separate container for the articles, which container holds the articles and wherein the two regulators are disposed external to the container.” The Examiner combines Doi with Ichihara relying on Ichihara for a teaching that sterilization of an article within its final packaging is known in the field of electron beam sterilization, but not for a teaching or suggestion of attaching a dose adjuster externally to a container that holds the articles.

In a response dated June 6, 2006, Applicant argued that Ichihara failed to teach or suggest attaching a dose adjuster externally to a container that holds the articles. In response to that argument, the Examiner presently asserts “[i]f Ichihara were to teach all that Applicant suggests is necessary, Ichihara would be an anticipatory reference.” The Examiner further asserts that “Ichihara was used in combination with Doi to illustrate the *obviousness* of first enclosing the articles sterilized by the method and apparatus of Doi.” The Examiner has not provided a source of any teaching or suggestion of placing a plurality of articles in a container and attaching a dose adjuster externally to the container.

Applicant asserts that for the Examiners rejection to be proper, the Examiner must provide a source for a teaching or suggestion of those missing features. The only possible source provided by the Examiner is Ichihara, which fails to provide such a teaching or suggestion. There are three basic requirements for presenting a sufficient *prima facie* case of obviousness, as outlined in MPEP § 2143. First there must be some suggestion or motivation to modify the reference or to combine reference teachings. Next, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all the claim limitations.

The missing features are not taught or suggested by Ichihara and the Examiner's statements provide support for that position. Because Ichihara does not teach or suggest the features that the Examiner admits are absent from Doi, the Examiner did not provide a proper *prima facie* case of obviousness. Therefore, independent claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43 and 46 are patentable over a combination of Doi and Ichihara.

Claim 3 depends from and includes all of the features of claim 1 and, for at least the same reasons, is patentable over Doi and Ichihara. Claim 6 depends from and includes all of the features of claim 4 and, for at least the same reasons, is patentable over Doi and Ichihara. Claim 9 depends from and includes all of the features of claim 7 and, for at least the same reasons, is patentable over Doi and Ichihara. Claims 11-13 depend from and include all of the features of claim 10 and, for at least the same reasons, are patentable over Doi and Ichihara. Claim 15 depends from and includes all of the features of claim 14 and, for at least the same reasons, is patentable over Doi and Ichihara. Claims 18-20 depend from and include all of the features of claim 17 and, for at least the same reasons are patentable over Doi and Ichihara. Claims 22-24 depend from and include all of the features of claim 21 and, for at least the same reasons are patentable over Doi and Ichihara. Claims 26-28 depend from and include all of the features of

claim 25 and, for at least the same reasons, are patentable over Doi and Ichihara. Claims 30 and 31 depend from and include all of the features of claim 29 and, for at least the same reasons, are patentable over Doi and Ichihara. Claims 33-35 depend from and include all of the features of claim 32 and, for at least the same reasons, are patentable over Doi and Ichihara. Claims 38-42 depend from and include all of the features of claim 37 and, for at least the same reasons, are patentable over Doi and Ichihara. Claims 44 and 45 depend from and include all of the features of claim 43 and, for at least the same reasons, are patentable over Doi and Ichihara. Claims 47-52 depend from and include all of the features of claim 46 and, for at least the same reasons, are patentable over Doi and Ichihara.

Claims 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi in view of Ichihara as applied to claims 15 and 32 above, and further in view of Peck et al. (U.S. 5,590,602). The Examiner relies on Peck for teaching a method and apparatus for electron beam sterilization of articles conveyed in spaced containers in a conveyor system.

As described above, in order to provide a proper *prima facie* case of obviousness, the Examiner is required to provide references that teach or suggest every recited feature in the rejected claims. Doi and Ichihara both fail to teach or suggest attaching a dose adjuster externally to a container that holds articles to be irradiated. The Applicant recognizes that the Examiner did not combine those references with Peck to teach that feature, but because that feature is missing in Doi and Ichihara, Peck has to provide a teaching or suggestion in order for the rejection to be proper. Peck fails to provide such a teaching or suggestion. As a result, the Examiner has not provided a sufficient *prima facie* case of obviousness. Therefore claims 16 and 36 are patentable over a combination of Doi, Ichihara and Peck.

Conclusion

It is believed this amendment now has placed the application in condition for consideration and allowance. If necessary, the Commissioner is hereby authorized in this and concurrent replies to charge payment (or credit any overpayment) to Deposit Account No. 50-0683 of Luce, Forward, Hamilton & Scripps.

Respectfully submitted,



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Date

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